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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,464	03/19/2002	Timothy A Bird	2923-US	1412

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EXAMINER	
MONSHIPOURI, MARYAM	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,464	BIRD ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *5,6,11-16 and 18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-10 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's response to lack of unity requirement filed 12/3/2004 is acknowledged. Applicant elected Group I invention (claims 1-4, 7-10 and 17) without traverse. Claims 5-6, 11-16, and 18-20 are withdrawn as drawn to non-elected invention.

DETAILED ACTION

Claims 1-4, 7-10 and 17 are under examination on the merits.

Specification

The disclosure is objected to because of non-compliance with sequence Rules. In pages 4-5 a series of figures are presented without specifying their corresponding SEQ ID NO:'s. Correction is required. See particularly 37 CFR 1.821(d).

Claim Rejections - 35 USC § 112

The following is a quotation of the first and 2nd paragraphs of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 7-9 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1(f) the structure of DNA sequences, having 80% or higher identity to homologs of DNA sequences that hybridize to DNA sequences recited in claim 1(c) is unclear. It is unclear as to how much identity should be considered for said DNA sequences. Claims 2-4 and 7-9 and 17 are merely rejected for depending from a rejected base claim.

Claims 1-4, 7-10 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acids encoding SEQ ID NO:11 or residues 57-309 of SEQ ID NO:11, vectors and host cells comprising said products and methods of expressing said products does not reasonably provide enablement for any of the following:

1) isolated nucleic acid molecules that are at least 80% identical to molecules of claims 1(a)-(e) encoding products with kinase activity.

(2) amino acids that retain at least 80% identity to SEQ ID NO:11 with kinase activity (see claim 10).

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The disclosure fails to teach the critical residues in the above mentioned DNA or polypeptide homologs such that said products either encode or retain kinase activity. No examples of such residues are provided either. Current state of prior art indicates that once more than 3-6 residues in either a DNA sequence encoding a full-length product with kinase activity or in a full-length polypeptide with kinase activity is deleted, substituted, mutated etc. said products do not necessarily retain their three dimensional structure such that they could either encode or retain kinase activity. Applicant is reminded that in claim 1(f), he/she is claiming DNA molecules comprising

DNA sequences that have at least 80% identity to DNA sequences that hybridize to DNA sequences encoding SEQ ID NO:11, having even less structural information than the other homologs claimed, thereby suffering from even further lack of enablement for the aforementioned reasons.

Therefore due to lack of sufficient teachings and examples provided in the disclosure and due to unpredictability of prior art as to structural requirements of homologs listed as 1-2 above, one of skill in the art has to go through the burden of undue experimentation in order to screen for those homologs that retain the appropriate conformation for either retaining or encoding kinase activity and as such the claims go beyond the scope of the disclosure. Claims 2-4, 7-9 and 17 are merely rejected for depending from a rejected base claim 1.

Claims 1-4, 7-10 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 10 are each directed to the following **genera** of homologs that have not been adequately described in the disclosure.

1) a **genus** isolated nucleic acid molecules that are at least 80% identical to molecules of claims 1(a)-(e) or their expression products with kinase activity.

(2) a **genus** of isolated amino acids that retain at least 80% identity to SEQ ID NO:11 with kinase activity (see claim 10).

(3) a genus of kinases comprising residues 215-247 (only 32 consecutive amino acids) of SEQ ID NO:11.

The disclosure fails to teach the structural requirements of the genera indicated above, such that said products retain the appropriate three dimensional structure to either encode kinase or retain said activity. The genera of cDNAs that comprise these above cDNA molecules, or comprise above mentioned polypeptide homologs with kinase activity is a large variable genera with the potentiality of having many diverse structures including many non-active or irrelevant embodiments. Therefore, many structurally unrelated DNAs and polypeptides are encompassed within the scope of claims 1 and 10.

Applicant is again reminded that in claim 1(f), he/she is claiming a genus of DNA molecules comprising DNA sequences that have at least 80% identity to DNA sequences that hybridize to DNA sequences encoding SEQ ID NO:11, thereby suffering from even further lack of adequate written description, as said products must have even less structural similarity than those recited in part (1) above.

In claim 10(c) the structural requirements is almost non-existent, because a fragment of 32 amino acids of SEQ ID NO:11 (247-215=32) is totally incapable of retaining any activity including kinase activity and the disclosure has not provided information about what the other constituents of claimed polypeptide must be such that it would have the kinase activity that is supported by instant application.

The disclosure provides only a **single species** for each claimed genus listed as 1-3 above (i.e. SEQ ID NO:4 and 11) which is insufficient to put one of skill in the art in

possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 2-4, 7-9 and 17 are merely rejected for depending from a rejected base claim 1.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

No claims are allowed.

Allowable Subject Matter

DNA sequences comprising SEQ ID NO:4 , or encoding SEQ ID NO:11 are free of prior art. Further, the prior art does not teach or suggest preparing such specifically claimed products. Hence said products are also non-obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 or (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maryam Monshipouri Ph.D.

Primary Examiner